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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,064	07/02/1999	JURGEN ECK	09282-5(B352	3271
570	7590	03/11/2004	EXAMINER	
AKIN GUMP STRAUSS HAUER & FELD L.L.P.			EWOLDT, GERALD R	
ONE COMMERCE SQUARE			ART UNIT	
2005 MARKET STREET, SUITE 2200			PAPER NUMBER	
PHILADELPHIA, PA 19103-7013			1644	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/347,064

Applicant(s)

ECK ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002 and 09 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 29, 33-37, and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 29, 33-37 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald Ewoldt, Art Unit 1644.
2. Claims 1-27, 29, 33-37, and 47-49 are being acted upon.
3. In view of Applicant's amendment and response, filed 4/29/02, the previous rejection under 35 U.S.C. 103(a) has been withdrawn. In particular, Applicant's argument that the primary reference (the '443 patent) did not teach a polynucleotide encoding the entire construct but rather a protein conjugate, was found convincing. Additionally it is noted by the Examiner that the Wu et al. reference is not available for use as prior art.
4. Applicant is advised that the application is now found to be fully sequence compliant. Accordingly, all objections and rejections based on lack of sequence compliance have been withdrawn, including the previous rejections under the first paragraph of 35 U.S.C. 112 for the introduction of new matter into the claims. Also, all previous rejections for inadequate antecedent basis in the specification have been withdrawn.
5. Applicant is advised that upon review the instant application has been granted the benefit of priority of EP 97 10 0012.0. Applicant is advised, to amend the first line of the specification to include the claim to said benefit.
6. The abstract, filed 4/29/02 has been found acceptable.
7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
8. Claims 9, 10, 12-14, 16, 24, and 25 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the paper mailed 10/22/01.

Applicant's arguments, filed 4/29/02, have been fully considered but they are not persuasive. Applicant argues that the cancellation of Claim 32 obviates the rejection of said claim.

Applicant has added new Claim 49, like Claim 32, drawn to a medicament. Accordingly, the rejection of canceled Claim 32 now applies to newly added Claim 49. Applicant has not traversed the actual grounds for the rejection.

Applicant argues "First, contrary to the Examiner's assertion, none of the claims is [sic] drawn to nucleic acids encoding fragments or derivatives of fusion proteins. Each of the claims is drawn to a nucleic acid encoding a fusion protein, which is itself made up of at least four portions or "modules." Thus, the Examiner's assertion that the specification does not enable a skilled artisan to make or use fragments/derivatives of the claimed fusion proteins is irrelevant and inapplicable, and therefore it will not be further addressed herein.

Whether the constructs of the instant claims are considered to be fusion protein fragments or a collection of fragments assembled into fusion proteins, Applicant's argument does not provide any additional significant enablement.

Applicant argues "guidance which is at least adequate to instruct the person of ordinary skill in the art regarding the specific properties of the nucleic acid molecules encoding a functional effector, processing, or modulating modulator is provided in the specification...Further information pertaining to means of determining whether a given protein exhibits the desired functionalities or properties is set forth in Examples 1 to 13."

It is the Examiner's position that Applicant is arguing that one of skill in the art might simply employ a method of trial and error to establish which fusion protein constructs might or might not be functional. As a method of trial and error would provide no particular expectation of success with any particular construct, the use of said method is considered to comprise undue experimentation.

Applicant argues "contrary to the position of the Examiner, there is no requirement under § 112, Wands, or any other patent statute or rule, that applicants inform the person of ordinary skill as to how to "predict" the precise structure of each and every molecule which falls within the scope of a given claim. An applicant is entitled to claim his inventive technology by any

means of his choosing.

Applicant's point in this line of argument is unclear. It is merely the Examiner's position that given the inherent unpredictability of physiological processes (see MPEP 2164.03), enablement commensurate with the scope of the claims is required. Given that the claims encompass an essentially unlimited number of fusion proteins comprising combinations of derivatives and fragments, said derivatives and fragments comprising deletions, substitutions, insertions, additions, and exchanges, it remains the Examiner's position that the specification fails to provide said enablement. Note that the enablement requirement requires that the specification disclose not just how to make an invention, but also how to use an invention. Accordingly, while it is obvious that one of skill in the art could produce the claimed fusion proteins (whether glycosylated or not) it is not obvious that one of skill in the art could use said products because the specification provides insufficient direction as to which of the limitless fusion products of the claims would be functional and which would not. As set forth above, Applicant's direction to try a method of trial and error is not sufficiently enabling as it provides no particular expectation of success in using any particular product.

9. Claims 1-27, 29, 33-37, and newly added Claims 47-49 stand/are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record set forth in the paper mailed 10/22/01.

Applicant's arguments, filed 4/29/02, have been fully considered but they are not persuasive. Applicant argues that "the written description requirement requires that the applicants' specification convey with reasonable clarity to those skilled in the art that, as of the filing date, he or she was in possession of the invention, i.e., whatever is now claimed".

It is the Examiner's position that Applicant has not provided sufficient evidence that Applicant was in possession of a representative number of the essentially limitless number of polynucleotides encoding fusion proteins comprising combinations of derivatives and fragments, said derivatives and fragments comprising deletions, substitutions, insertions, additions, and exchanges, nor the polynucleotides that would hybridize to said

polynucleotides encoding fusion proteins.

10. Claims 10-14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In claims 10-11, the recitation of the phrase "a cell of the specific immune system" has not been defined in the specification and thus renders the claims ambiguous and indefinite.

B) In claim 13, the recitation of the phrase "a cell of the unspecific immune system" has not been defined in the specification and thus renders the claim ambiguous and indefinite.

C) In claim 14, the recitation of the phrase "a degenerate cell of the immune system" has not been defined in the specification and thus renders the claim ambiguous and indefinite.

Applicant's arguments, filed 4/29/02 have been fully considered but they are not persuasive. Applicant argues that the terms would be well-known to one of skill in the art. Applicant further argues that the "unspecific immune system" really means the "non-specific immune system" and comprises merely an "inartful translation" of the term.

Applicant's assertions comprise only attorney's argument; said argument cannot be considered evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. Additionally, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP 2145. Accordingly, the rejections are maintained.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

14. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


3/9/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER